CLIA Updates

Montana CLIA Program

7/1/15

IQCP

Does it apply to you?

The education period for the change from Equivalent Quality Control (EQC) to an Individualized Quality Control Plan (IQCP) began January 1, 2014. The education period for labs will end January 1, 2016, at which point all labs must comply with the standard federal regulations or have the IQCP policy and documentation already implemented. EQC will no longer be an acceptable method of quality control (QC) after January 1, 2016.

Does IQCP apply to you?

Do you already perform **EQC** for any tests/analyzers? This includes any non-waived test/analyzer with less QC than CLIA regulations require, usually two levels of different concentrations each day of testing.
If you answered "yes" to this question, then you need to pay attention to IQCP and have the new policy and procedure implemented prior to January 1, 2016.

Your IQCP policy must include all three required sections.
1) A Risk Assessment
2) A Quality Control Plan
3) A Quality Assurance Monitor

Most laboratories with Certificates of Compliance will be affected by this change. IQCP will not apply to waived tests, Certificates of Waiver, or Certificates of Provider Preformed Microscopy. Except Pathology and Cytology, it can apply to non-waived tests. Don't forget this includes testing on non-waived kit tests.

Writing an IQCP policy does take time so now is the best time to get started on your IQCP Policy!

A workbook has now been released! See below.

Inside this issue:

Where can I find resources about IQCP?

There are multiple CMS publications with information on IQCP.

The original Survey & Certification policy # 13-54 CLIA from CMS was published on 10-31-2014. This letter includes the new text that will be incorporated in the Interpretive Guidelines in place of EQC in January 2016.

There are three CLIA brochures also published by CMS to help you understand IQCP.

There is also a CMS workbook to assist you in writing your IQCP policy. This contains examples and template worksheets to use when writing IQCP.

Download from: www.cms.gov/clia under the "Individualized Quality Control Plan" tab on the left side of the page. At the bottom are all resources including Brochure #11, 12, and 13, Survey & Cert Letter 13-54, and **IQCP Workbook**.

Special points of interest:

- IQCP = Individualized Quality Control Plan
- IQCP guidelines are found online at cms.gov/CLIA
- Implements January 1, 2016
- Be prepared to write all 3 required sections in your IQCP Policy

What are the Basic CLIA QC Regulations anyway?

§493.1256: Control procedures.

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process.

(b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in §493.1253(b)(3).

(c) The control procedures must—

(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance.

(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

(d) Unless CMS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must—

(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at §§493.1261 through 493.1278.

(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section.

(3) At least **once each day** patient specimens are assayed or examined perform the following for—

(i) Each quantitative procedure, include **two control materials of different concentrations**;

(ii) Each qualitative procedure, include a **negative and positive** control material;

(iii) Test procedures producing graded or titered results, include a negative control material and a control material with **graded or titered** reactivity, respectively.

For specific subspecialty QC requirements, see the regulations written in 493.1256(d)(3)(iv) to 493.1271(f).

Follow the CLIA QC regulations. If the manufacturer requires less QC, write your IQCP Policy before you reduce the QC for any test.

If you perform less QC than these regulations state, then you may be performing EQC. Please take note that EQC will no longer be a compliant option after January 1, 2016.

You have two options after January 1, 2016:

1) Follow the CLIA regulations or,
2) Write an IQCP Policy to perform less QC than required by CLIA.

Please note the following:
1) The minimum allowable QC for your IQCP policy is the manufacturer's requirements. You cannot perform less QC than what the manufacturer recommends.

2) IQCP will not apply to waived testing.

3) IQCP will affect most laboratories with Certificates of Compliance.

Release of New Interpretive Guidelines- Did you know?

On January 9, 2015, CMS released an advanced version of the Interpretive Guidelines. This 2015 version has **many changes** to the interpretation of the federal regulations. However, it still has EQC in the QC section as a compliant option until it is replaced by IQCP in January 2016.

There may be minor changes made to the document when IQCP is incorporated and published in January of 2016 at which point IQCP becomes the only compliant option to reduce QC.

The last version of the Interpretive Guidelines was released in 2004.

You can find the new advanced version of the Interpretive Guidelines at www.cms.gov/CLIA under the tab on the left side of the screen titled "Interpretive Guidelines For the Laboratories." A version of Interpretive Guidelines with IQCP will be released in January of 2016.

What is PT Referral?

The regulations about Proficiency Testing (PT) are very strict. The federal regulations forbid proficiency testing samples to be sent to another laboratory (separate CLIA certificate) for testing. This includes affiliated laboratories with the same director/owner/employees.

§493.801: Enrollment and Testing of Samples

*(b)(4) The laboratory **must not send** proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least 1 year. Any laboratory that **receives a proficiency testing sample** from another laboratory for testing **must notify** CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.*

If a lab has its own CLIA number, it is responsible for enrolling in proficiency testing for that CLIA number, testing the samples within that specific lab, and submitting results under that specific lab's CLIA number. Collaboration or discussion of the results is forbidden until after the submission deadline.

§493.801: Enrollment and Testing of Samples

*(b)(3) Laboratories that perform tests on proficiency testing samples **must not engage in any inter-laboratory communications** pertaining to the results of proficiency testing sample(s) **until after the date** by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories **with multiple testing sites or separate locations** must **not participate** in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program).*

Please take a few minutes to evaluate your proficiency testing system to ensure that no proficiency testing samples are sent to another laboratory with a separate CLIA number for testing or for confirmatory measures. Also, ensure that all results are only reported for the proper CLIA number.

Now is a good time to remind all of your staff about the rules of proficiency testing. All testing personnel and the Lab Director sign an attestation form attesting to following the rules of proficiency testing.

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S&C Memos Are CMS's Communication To You!

CMS releases Survey and Certification (S & C) memos sporadically with information on changes and updates for CLIA.

This information is freely available online for the public.

S & C letters can be found online at:

http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html

S & C letters for all provider types are located here. To find CLIA specific information,

Type "CLIA" into the filter box.

Organize them by "Memo #" to get the most recently published S & Cs.

S & Cs are released as necessary so check the site regularly for the latest CMS communications.

All recent changes outlined in this newsletter (IQCP, Micro, new IGs) have been released through S & C memos.

Removal of CLSI from the Interpretive Guidelines - TAKE NOTE!

Please take note that Survey & Certification Policy #15-07; "Effect on Microbiology Laboratories Due to the Removal of References to the Clinical Laboratory Standards Institute (CLSI) and to CLSI Documents" will affect laboratories performing the specialty of microbiology. Additional microbiology control requirements can be found at ***§493.1256(e)(1).***

Removal of the CLSI documents from the Interpretive Guidelines will change two areas of microbiology:

1) Keeping the shipping receipt to document media conditions will no longer be sufficient to meet the sterility and growth regulations at 493.1256(e). Labs will be required to meet the CLIA regulations which require plate sterility, growth, and media physical characteristics be performed and documented for each batch of **all** plate types.

§493.1256: Control procedures

(e)(4) Before, or concurrent with the initial use--

*(e)(4)(i) Check each batch of media for **sterility** if sterility is required for testing;*

*(e)(4)(ii) Check each batch of media for its ability to **support growth** and, as appropriate, **select or inhibit** specific organisms or **produce a biochemical response**; and*

*(e)(4)(iii) Document the **physical characteristics** of the media when compromised and report any deterioration in the media to the manufacturer.*

*(e)(5) Follow the **manufacturer's specifications** for using reagents, media, and supplies and be responsible for results.*

Most laboratories currently perform sterility and growth solely on chocolate agar, Campylobacter agar, and Neisseria selective media. The CLSI tables in the Interpretive Guidelines allowed all other media (Blood, MacConkey, Thioglycolate medium, etc) to use the shipping receipt as evidence of sterility and growth as long as physical characteristics of the media was documented. This exception is no longer considered compliant with the federal regulations as of January 9, 2015.

Please **begin documenting** media sterility, growth/inhibition of growth/selection (dependent on media type), as well as media characteristics for the next batch of media you order.

2) Weekly QC for microbiology sensitivities will no longer be compliant with the CLIA regulations at 493.1261(b).

§493. 1261: Bacteriology

(b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms.

*(b)(1) **Each day** tests are performed, the laboratory must use the **appropriate control organism**(s) to check the procedure.*

*(b)(2) The laboratory's zone sizes or minimum inhibitory concentration f or control organisms must be **within established limits** before reporting patient results.*

*(c) The laboratory must **document** all control procedures performed, as specified in this section.*

Labs will be required to meet daily QC requirements for sensitivities. Labs wishing to reduce QC on sensitivities to less than day of testing will be required write an **IQCP policy**. The QC cannot be reduced to less than the manufacturer's recommendations.

Take note that the 20-day study discussed in the Survey & Certification memo #09-06 that was previously distributed by the CLIA surveyor is no longer valid but can be used to support an IQCP policy.

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The fuss about GLUCOMETERS

CMS released S & C #15-11 for "Off-Label/Modified Use of Waived Blood Glucose Monitoring Systems (BGMS)." You can download it from the website listed on the bottom of page 3 of this newsletter.

BGMS (glucometers) were originally designed and approved by the FDA as a consumer device for monitoring known diabetic patients. However, the use of glucometers has expanded into many healthcare settings with use on patient populations not addressed in the original studies approved by the FDA. This announcement applies only to glucometers and not to other point-of-care instruments capable of reporting glucose results. Since glucometers are classified as waived by the FDA, the federal regulations require:

§493. 1252: Test Systems, Equipment, Instruments, Reagents, Materials, and Supplies

*(a) The testing must be performed **following the manufacturer's instructions** and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under §493.1253.*

Failure to follow the manufacturer instructions constitutes off-label use which results in the glucometer defaulting to a non-waived **HIGH** complexity test. All requirements in the federal regulations in 42 CFR 493 subparts H, J, K, M, and Q will then apply, including establishing performance specifications (i.e., accuracy, precision, analytical sensitivity, analytical specificity including interfering substances, reportable range of test results, and reference intervals). Following the manufacturer instructions will retain the glucometer as a waived test.

All CLIA certificate holders (Waiver, PPMP, and Compliance) with a glucometer **need to critically read the manufacturer instructions and follow them**. Key information to extract from the instructions include: the **intended patient population, intended use of the instrument, approved sample type, limitations, and precautions**. Determine if the *intended patient population* is exclusively for known diabetic patients, if it is approved for screening patients, or approved for use in a healthcare setting. Establish if the *intended use* is for single patient use, multi patient use, or at home use. The *sample type* will indicate if the glucometer is approved for finger sticks, venous blood, arterial blood, or neonatal heal sticks. Also, pay attention to *limitations and precautions* which could be listed in different areas. A few examples of limitations that you may see include shock, dehydration, a specific range of acceptable hematocrits, oxygen saturation, temperatures, or may include vague terms that state it is not for use on "critically ill" patients. If the insert mentions the limitation for critically ill, the facility must define what "critically ill" means for the facility. CMS will not define that term.

Take a few minutes to ensure your facility has a glucometer specific policy that defines each of those areas for your specific glucometer make and model. Determine if the manufacturer instructions **match how the facility is using the glucometer**. Then, document any necessary training to refresh all employees who use the glucometer of the manufacturer instructions.

For an example of off-label use and for more information, see the S & C Memo #15-11.

Change the Policy and Procedure Manual Immediately!

In the advanced version of the Interpretive Guidelines, there is a change in the person allowed to approve the laboratory policy and procedure manuals. The interpretive guidelines state:

§493.1407 Laboratory director responsibilities

(e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

Interpretive Guidelines §493.1497(e)(13)

*The laboratory director can delegate to the technical supervisor the responsibility of making the procedure manual available, but **cannot delegate the responsibility for signing new and revised procedures**.*

If your policies and procedures are currently signed by a technical consultant or laboratory manager, please require your current **laboratory director to sign and approve** the policy and procedure manual immediately.